Patient safety & satisfaction with Electroacupuncture in a teaching clinic, a survey of interns and patients

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ABSTRACT:

Acupuncture, including electroacupuncture, is an important modality in TCM therapies. Acupuncture is increasingly used in Europe and North America. Its widening acceptance demands continual safety assessment. This pilot study was to evaluate the frequency and severity of adverse events (AEs) for electroacupuncture in a teaching clinic.

Needle-only acupuncture has a high patient satisfaction rate and low adverse event (AE) rate.

Our study demonstrated that the satisfaction with and safety of electroacupuncture and needle-only acupuncture are similar.

Description:

While standard acupuncture has been shown to have a high patient satisfaction rate (1,2) and low adverse event rate (3,4), there is a paucity of information about electroacupuncture. We designed this prospective study in order to evaluate whether the satisfaction with and safety of the two types of acupuncture are similar. There are very few studies of the potential adverse effects of electro-acupuncture (EA). One recent review of the literature from 1979-2010 found only 44 incidences of AE reported during that time frame in either English or Chinese databases. (4) While a number of the AE were probably associated with the acupuncture (faintness, hyperventilation) a few were associated with the application of an electrical current (electrical injury, atrioventricular block, dislocation of the wrist joint from muscle spasm). (4,5)

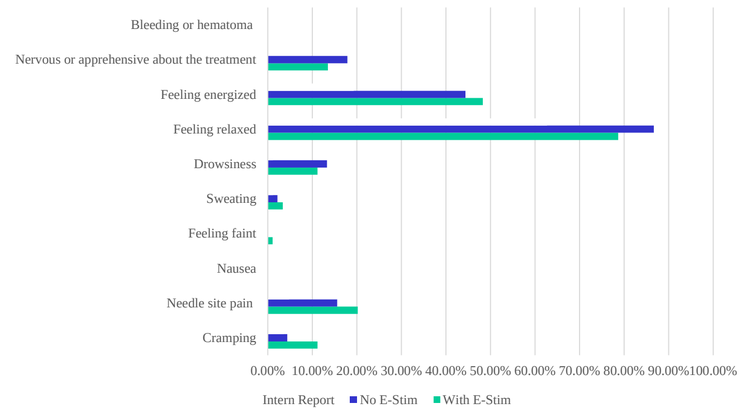
In order to match earlier studies on acupuncture safety, such as the SAFA study by White et al,(3) we defined adverse events to be any ill effect that is unintended and non-therapeutic. This included errors, non-serious events such as minor bleeding, and any serious events.

Our aim was to determine if the rate of errors, incidences and adverse events are similar for electroacupuncture when compared to needle only acupuncture in a teaching clinic setting.

Outcomes

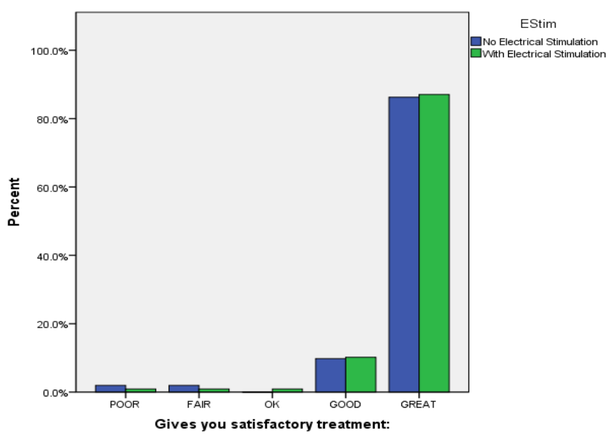
Event:	Patient Report With E-Stim	Patient Report No E-Stim	Effect Size (Cohen)	Intern Report	White SAFA Study (2001)	McPherson Study (2005)
Cramping	11.2%	4.4%	0.257	3.6%		0.5%
Needle site pain	20.2%	15.6%	0.087	4.8%	1.1%	12%
Nausea	0.0%	0.0%	NA	0.0%		1.2%
Feeling faint	1.1%	0.0%	NA	Not reported	0.29%	2.6%
Sweating	3.4%	2.2%	0.072	1.2%	0.1%	0.8%
Drowsiness	11.2%	13.3%	0.093	1.2%	0.3%	0.6%
Feeling relaxed	78.7%	86.7%	0.274	62.7%		79.1%
Feeling energized	48.3%	44.4%	0	19.3%		32.7%
Nervous or apprehensive about the treatment	13.5%	17.9%				
Patient identified likelihood of returning for additional treatments?	91%	88%				99%
Total Negative Reactions:	38%	30%			7%	29.7%
Bleeding or hematoma				3.6%	3%	4.7%

Comparison of EStim, No Estim, Intern Reports of AE



Intern Reports of Errors and Events:

3 (3.6%)	*Visible bruising*
1 (1.2%)	*Swelling at an acupuncture point*
2 (2.4%)	*Bleeding lasting 10 seconds or longer*
3 (3.6%)	*Dropped needle*
0 (0.0%)	*Lost needle (needle in count did not correlate with needles removed)*
1 (1.3%)	*Trouble removing a needle*
0 (0.0%)	*Needlestick*
3 (3.6 %)	*Other incident requiring supervisor assistance (describe): trouble locating point; trouble getting de qi; needed help keeping needle in skin with electrodes attached.*



Discussion

In this study both the patients receiving e-stim acupuncture and no e-stim acupuncture were equally satisfied with their treatments. There were no significant adverse events associated with either arm of the study.

In the e-stim acupuncture group there was a trend toward there to be more pain and cramping reported than in the no e-stim acupuncture group. Of these two findings, only the cramping showed an effect size of greater than 0.2 and therefore only a small clinical difference. It is possible that this is a true finding, given that e-stim is known to cause muscle cramping at certain settings. It is also possible that this was due to the choice of patients that received e-stim acupuncture (supervising clinicians had the option to identify whether the patients needed e-stim or not), the heavier gauge needles and deeper needle placement that are often used to support the electrodes utilized for the electrical stimulation.

Those patients not receiving e-stim acupuncture tended to be more relaxed than those in the e-stim group.

Those patients not receiving electrical stimulation did trend toward being more relaxed about the procedure than those who participated in the e-stim arm of the study. This difference was small and had no impact on patient satisfaction.

There were no other reported adverse reactions that were statistically different between the two groups.

Of note, there was a significant discrepancy between the patients' reports of needle site pain, cramping and drowsiness compared to the interns' impressions of the outcomes. Whether this is due to the nature of being a teaching clinic or whether this is due to patient reticence about voicing concerns about treatment is unclear.

Comparison of the outcomes with other well-known studies of acupuncture safety (White 2002 and McPherson 2005) also demonstrated that there were more pain and cramping overall in the student clinical setting but otherwise the safety of e-stim acupuncture compared well with standard acupuncture. Bleeding and bruising at the time of treatment were very similar (3.6-4.7%).

Patient satisfaction was high in all groups.

The total number of patients enrolled in this study was small, limiting the ability to show significant differences between the two groups. The small size also limited the likelihood of rare serious adverse events of acupuncture (local site infection, pneumothorax) from being seen in this population. However, due to the similar outcomes with the McPherson study, there is a high likelihood that acupuncture with electrical stimulation compares favorably with standard acupuncture in terms of safety and patient satisfaction.

T Test

Group Statistics

	EStim	N	Mean	Std. Deviation	Std. Error Mean
Gives you satisfactory treatment:	No Electrical Stimulation	51	4.76	.737	.103
	With Electrical Stimulation	108	4.81	.582	.056
Feeling Relaxed	No Electrical Stimulation	52	.75	.437	.061
	With Electrical Stimulation	112	.63	.486	.046
Feeling Energized	No Electrical Stimulation	52	.38	.491	.068
	With Electrical Stimulation	112	.38	.489	.046
Feeling Drowsy	No Electrical Stimulation	52	.12	.323	.045
	With Electrical Stimulation	112	.09	.286	.027
Feeling Pain	No Electrical Stimulation	52	.13	.345	.048
	With Electrical Stimulation	112	.16	.369	.035
Cramping	No Electrical Stimulation	52	.04	.194	.027
	With Electrical Stimulation	112	.09	.286	.027
Sweating	No Electrical Stimulation	52	.02	.139	.019
	With Electrical Stimulation	112	.03	.162	.015
Feeling Faint	No Electrical Stimulation	52	.00	.000	.000
	With Electrical Stimulation	112	.01	.094	.009

Conclusions: acupuncture with electrical stimulation compares favorably with standard acupuncture in terms of both safety and patient satisfaction.

References

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